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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,972	04/21/2004	Rex A. Niles	223P164	5414
33831	7590	02/07/2005	EXAMINER	
HANCOCK & ESTABROOK, LLP 1500 MONY TOWER I PO BOX 4976 SYRACUSE, NY 13221-4976			PATTEL, MITAL B	
		ART UNIT		PAPER NUMBER
				3743

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/828,972	NILES ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Mital B. Patel	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 April 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
  - 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 April 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/21/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to a nebulizer head, classified in class 128, subclass 200.14.
  - II. Claim 10, drawn to a method of selectively introducing a supplemental gas into a nebulizer, classified in class 128, subclass 200.24.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by another materially different apparatus. It should be noted that that process does not require the particulars apparatus of Group I, i.e., another materially different nebulizer/atomizer may be used to practice the process.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
6. During a telephone conversation with Mr. Roehrig, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claim 10 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Specification***

8. The disclosure is objected to because of the following informalities: It should be noted that a brief description of Figure 1 is missing.  
  
Appropriate correction is required.

#### ***Drawings***

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for

selectively closing the auxiliary gas inlet port must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Briggs, III (US 6,041,776).

12. As to claim 1, Briggs, III teaches a nebulizer head **12,12a** (See Figs. 1 and 2) having an auxiliary gas inlet port **52, 52a** for introducing a supplemental gas, comprising: a first chamber (See Figs. 1-2) having a closed top, enclosing sides and an open bottom adapted to receive for coupling thereto a receptacle **14,14a** adapted to contain a liquid medicant **42,42a** to be dispensed at a predetermined rate of concentration; a second nebulizing chamber **26,26a** carried within said first chamber at a position spaced from said closed top and extending downwardly therefrom; said nebulizing chamber having an open bottom adapted to pass outwardly therethrough entrained and nebulized liquid medicant; a nebulizing nozzle **36,36a** in fluid communication with said nebulizing chamber for creating a nebulized aerosol from liquid medicant coupled thereto; means **38,38a** for coupling a flow of nebulizing gas into said first chamber to said nebulizing nozzle and through said second nebulizing chamber carried within said first chamber; an aspirator tube **40,40a** having a first end positioned in fluid communication adjacent to said nebulizing nozzle, and a second end positioned to be received into liquid medicant contained within the receptacle; an auxiliary gas inlet **52,52a** port for introducing a supplemental gas into said first chamber extending into said first chamber at a position removed from the interior of said nebulizing chamber; and said first chamber having a discharge outlet **50** spaced from said open bottom of said nebulizing chamber and said auxiliary gas inlet port for discharging liquid medicant

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entrained in said nebulizing chamber and the supplemental gas introduced into said first chamber through said auxiliary gas inlet port.

13. **As to claim 2**, Briggs, III teaches a nebulizer head wherein said auxiliary gas inlet port and said discharge outlet are in opposed positions relative to each other, and said nebulizing chamber carried within said first chamber extends therebetween (**See Figs. 1 and 2**).

14. **As to claim 3**, Briggs, III teaches a nebulizer head further including a receptacle **14,14a** for containing liquid medicant to be dispensed through said discharge outlet.

15. **As to claim 4**, Briggs, III teaches a nebulizer head wherein said receptacle includes means **46,46a** for releasibly connecting said receptacle to said first chamber in sealing engagement therewith.

16. **As to claim 5**, Briggs, III teaches a nebulizer head wherein said nebulizing chamber has an open top attached to the interior of said first chamber at a position above said auxiliary gas inlet port and said nebulizing chamber extends downwardly therefrom such that said open bottom of said nebulizing chamber is positioned at a location removed from said auxiliary gas inlet port (**See Figs. 1-2**).

17. **As to claim 6**, Briggs, III teaches a nebulizer head wherein said nebulizing nozzle is supported from said first chamber top above said nebulizing chamber for entraining liquid medicant communicated thereto through said aspirator tube (**See Figs. 1-2**).

18. **As to claim 7**, Briggs, III teaches a nebulizer head wherein said nebulizing chamber extends downwardly within said first chamber such that said open bottom of

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said nebulizing chamber is positioned at a location below said auxiliary gas inlet port and below said first chamber discharge outlet (**See Figs. 1-2**).

19. **As to claim 8**, Briggs, III teaches a nebulizer head wherein said means for coupling a flow of nebulizing gas into said first chamber comprises an adapter **38,38a** for releasably coupling a source of driving gas to said nebulizing nozzle.

20. **As to claim 9**, Briggs, III teaches a nebulizer head wherein said auxiliary gas inlet port includes means **56** for selectively closing said auxiliary gas inlet port when not in use.

### ***Conclusion***

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6328030, US 5823179, US 5119807, US 4792097, and US 3353536.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Mital B. Patel  
Examiner  
Art Unit 3743

2/6/05